NASA Procedural Requirements

NPR 7100.1
Effective Date: March 28, 2003
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COMPLIANCE IS MANDATORY

Protection of Human Research Subjects

Responsible Office: Office of the Chief Health & Medical Officer

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Preface

P.1 PURPOSE

P.1.1 This NASA Procedural Requirements(NPR) outlines the implementing procedures and guidelines for the Agency to conduct or support research involving human subjects.

These guidelines follow the provisions of "Federal Policy for the Protection of Human Subjects" as codified for NASA in Title 14 CFR Part 1230, and for the U. S. Department of Health and Human Services (DHHS) in Title 45 CFR Part 46. These regulations are implemented by the DHHS, Office for Human Research Protections (OHRP).

P.1.2 The primary intent of these guidelines is to provide instructions on setting up oversight protection for the rights, medical safety, and well-being of human subjects involved in research. This shall cover all volunteers who participate in any research utilizing NASA facilities, including NASA aircraft and spacecraft, directed by NASA personnel or onsite contractors, and in any NASA-conducted or supported research.

P.2 APPLICABILITY

P.2.1 These Requirements apply to NASA Headquarters (HQ), and all NASA Centers and component facilities engaged in experiments involving human subjects conducted or supported by NASA, conducted in NASA facilities, aircraft and spacecraft, or which involve NASA to any degree. The terms and conditions of this NPR, as applicable, are required to be incorporated in any contract, cooperative agreement, grant, or reimbursable arrangement, which involves human subject research entered into by NASA and another Government agency, private entity, non-Federal public entity, or foreign entity.

P.3 AUTHORITY

a. 42 U.S.C. 2473(c)(1), Section 203(c)(1) of the National Aeronautics and Space Act of 1958, as amended.

b. 14 CFR Part 1230, Protection of Human Subjects.

c. 45 CFR Part 46, Protection of Human Subjects.

P.4 REFERENCES

a. 5 U.S.C. 552, The Freedom of Information Act (FOIA), as amended.

b. 5 U.S.C. 552a, The Privacy Act of 1974, as amended.

c. NPD 8621.1H, NASA Mishap and Close-Call Reporting, Investigating, and Recordkeeping Policy.

d. NPR 1441.1D, NASA Records Retention Schedules.

e. NPD 8900.1F, Medical Operations Responsibilities in Support of Human Space Flight Programs.

f. NPD 8900.3F, Astronaut Medical and Dental Observation Study and Care Program.

g. NPD 7100.8D, Protection of Human Research Subjects.

h. NPR 8621.1, NASA Procedures and Requirements for Mishap Reporting, Investigating, and Recordkeeping.

P.5 CANCELLATION

None.

/s/ Richard Williams, M.D.
Chief Health and Medical Officer

CHAPTER 1. Responsibilities

The purposes of this NPR is to comply with the following:

1.1 Authorized NASA Official (ANO):

The ANO shall be responsible for the protection of human subjects and is empowered, subject to conditions and limitations imposed by immediate superiors, to authorize research involving human subjects. All or part of the authority may be redelegated, without power of further redelegation, to (a) a senior NASA Hq employee who reports to the ANO, or (b) the NASA Center Director(s).

1.2 Inform the Administrator:

The ANO shall ensure that the Administrator, the appropriate Associate Administrators (AA) sponsoring research involving humans, the AA for Office of Safety and Mission Assurance (OSMA), and NASA Chief Scientist, are kept fully and currently informed, through official channels, of significant actions, problems, or other matters of substance related to the exercise of this authority.

1.3 Approval of Multiple Project Assurances (MPA):

The ANO is responsible for approving all NASA Center MPA's or Single Project Assurances (SPA), indicating that NASA-conducted or -sponsored research complies with NASA policy and the body of existing law pertaining to research involving human subjects. The ANO is responsible for approving each NASA Center's annual summary of the research and Institutional Review Board (IRB) activities for the preceding year including review of compliance activities, membership, initial and continuing education, and an updated IRB membership list.

1.4 NASA Center Directors

Shall be responsible for ensuring that their MPA is filed with the ANO. For NASA Center Directors not filing an MPA or SPA, the Center Director must certify to the ANO that research involving human subjects will not be conducted or sponsored by that Center during the following calendar year.

1.5 Establish IRB:

The NASA Center Directors may establish a Center IRB to review all ground-based, aerospace, and aeronautical flight research that their respective Centers conduct or that utilize NASA facilities, equipment, or personnel (NASA-conducted or -sponsored research). If this is not done, then another NASA IRB, by prior arrangement, shall review the research proposals using human subjects.

1.6 Protection of Rights:

The NASA Contracting Officers (NCO) shall ensure that all research proposals involving human subjects (including grants, contracts, cooperative agreements, memoranda of understanding, or other similar legal arrangements) are reviewed by an approved IRB prior to funding. The NCO shall maintain a record of all such IRB approvals.

1.7 Other Institutions Responsibilities:

Academic institutions, nonprofit institutions, or business enterprises performing NASA-funded research involving human subjects at non-NASA facilities, and not involving NASA permission to use Government equipment are responsible for obtaining approval for their proposed research from an approved IRB, which will generally be the IRB at the institution performing the research. NASA reserves the right to have all such research reviewed by a NASA IRB prior to funding or implementation of this research involving human subjects.

CHAPTER 2. NASA Institutional Review Boards (IRB)

2.1 IRB Authority

2.1.1 The IRB has authority to approve, disapprove, or require changes in the proposed research protocols and procedures involving human subjects covered by this NPG. Another authority cannot overturn a decision of disapproval; however, a decision of ANO, Center Director, or their designee may change a decision of approval to disapproval.

The IRB may conditionally approve a protocol or recommend changes to disapproved protocols that could result in protocol approval. Any changes must be approved by the IRB prior to initiation or continuation of the protocol. The IRB has the authority to suspend or terminate its approval of research activities that are not being conducted in accordance with the approved protocol, or the policies set forth in this NPG, or that have been associated with serious harm to human subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be promptly reported to the PI, the NASA Center Director, and the ANO. If an IRB disapproves, suspends, terminates, or conditionally approves a research activity, the PI shall be given the opportunity to respond to the decision by either meeting with the IRB or through written correspondence with the Chairperson of the IRB.

2.1.2 When a NASA Center funds research involving human subjects not involving NASA facilities, personnel or equipment, the Center IRB may evaluate such proposals prior to their funding, or the NASA IRB may accept IRB certification for the research proposal from a DHHS OHRP approved non-NASA IRB.

2.2 IRB Responsibility

The primary responsibility of the IRB is to protect the rights and ensure the safety of every person who is a research subject in any NASA facility, including NASA aircraft or spacecraft. This applies to subjects involved in any research conducted or supported by NASA.

2.3 IRB Functions

2.3.1 The IRB reviews all proposals for NASA-conducted or -sponsored, ground-based, aeronautical, and space flight research, that apply to human subjects (the latter applies to the NASA Flight IRB (NFI) only chapter 6), prior to funding, approval, or execution of research. Except when an expedited review procedure is used, this review of proposed research shall be held only at convened meetings at which a majority of the members of the IRB are present including at least one member whose primary concerns are in a nonscientific area. For the research to be approved by the IRB, it must receive the approval of a majority of those members present at the meeting. If human subjects are to participate in multiple research protocols at the same time, the IRB shall review all the research proposals as an integrated protocol to assess the risks and benefits to the research subject.

2.3.2 The IRB conducts a continuing review of research involving humans at intervals appropriate to the degree of risk, but not less than once per year. This continuing review shall include the informed consent particulars, the adequacy of safety precautions taken to date, and a determination as to whether or not proper and comprehensive information was given to the subject during the process. The IRB shall review all adverse events (whether expected or not), which occur during the conduct of research. In all cases in which there has been an adverse incident reported to the IRB, the IRB must notify the appropriate NASA safety and legal representatives, the ANO, and if appropriate other AA's.

2.3.3 The IRB defines for each approved experiment the extent to which the actual consent process and/or the conduct of the research shall be monitored. If monitoring is deemed necessary, this may be accomplished by appointment of a monitor with specified responsibilities or direct monitoring by selected members of the IRB.

2.3.4 The IRB maintains documentation of IRB activities as prescribed in chapter 6 of this NPR.

2.3.5 The appropriate NASA IRB must review and monitor non-NASA research using NASA facilities, equipment, or personnel involving human subjects.

2.3.6 The appropriate NASA IRB shall review human-used, ground-based simulators. The IRB shall determine the potential risks of the simulator operations to the research subjects. The IRB may then determine that all or some of the operations in the simulator may be IRB exempt, requires expedited review or requires full IRB review.

2.3.7 The ANO or designee will be responsible for developing and administering a NASA Human Protection Training program that is congruent with requirements for Federal funding by DHHS. This or similar training will be mandatory for all NASA IRB members and investigators using human subjects receiving NASA funds or involved in NASA-sponsored research.

2.3.8 The NASA Center IRB overseeing any human subject research for units responsible to that Center shall be responsible for appropriate oversight.

CHAPTER 3. Center IRB Membership

3.1 Membership Requirements

Each IRB shall have at least five members. The IRB shall consist of persons of varying backgrounds knowledgeable of the experimental environment and conditions to provide a complete and adequate review of research activities conducted by the institution or investigator. The IRB members shall be experienced, possess adequate expertise, and sufficient familiarity to exercise due diligence and consideration in the sensitive matters of race, gender, ethnic, and cultural backgrounds, and prevalent community attitudes toward human experimentation, to promote respect for IRB advice and counsel in safeguarding the rights and welfare of human research subjects. The cognizant NASA Center Director shall appoint the members of the IRB and select a full-time, senior-level NASA employee as the Chairperson. The members must have the competence required to review the research activities involving human subjects covered by this NPG and to determine the acceptability of the proposed research relative to applicable laws, safety regulations, health standards, and ethical codes. The Chairperson shall designate one of the members as his or her alternate.

3.2 Cultural Diversity

The IRB shall include culturally diverse members not entirely of one gender or race and shall include (1) a member of the Center's Safety and Mission Assurance Office; (2) at least one member whose expertise is in a nonscientific area such as medical ethics; (3) at least one member cognizant of the operational aspects of the aerospace or aeronautic environment if appropriate; (4) at least one member who is not otherwise affiliated with NASA who is not a part of the immediate family of a person affiliated with NASA; and (5) a subject representative. In the case of Johnson Space Center (JSC) IRB, an astronaut usually serves in this function. The JSC IRB shall also include a NASA-employed physician. The Center Office of Chief Counsel shall provide legal advice to the IRB.

3.3 IRB Conflict of Interest

No IRB member may participate in the review of any proposal in which that member has a conflicting interest, except to provide information requested by the Board.

3.4 Nonvoting Expert Consultation

The IRB may invite nonvoting experts to help review and resolve special or difficult issues which require competence beyond or supplementing that available on the Board.

3.5 Recording Secretary

The recording secretary shall be appointed by the Chairperson of the IRB for recordkeeping and for general administrative Board functions.

3.6 Term of Appointment

IRB members shall be appointed for a 3-year term and can be reappointed at the end of their term. The Center Director cannot remove IRB members from their positions before the end of their terms except in cases of misconduct.

CHAPTER 4. NASA IRB Convening Authority

Meetings shall be convened by the Chairperson of the IRB on a regular basis or when a request is made by the Director of Bioastronautics Research Division (DBRB), Office of Biological and Physical Research (OBPR); the Chief Health and Medical Officer (CHMO), NASA HQ; the Mission Manager; a NASA Center Director; or a test subject to evaluate a research protocol which may affect the health or well-being of participating human subject(s).

CHAPTER 5. NASA IRB Records

5.1 Preparation and Maintenance of Records

The IRB shall prepare and maintain documentation of its activities including the following:

5.1.1 Copies of all research proposals reviewed; scientific evaluations, if any, that accompany the proposals approved; final consent documents; progress reports submitted by PI's; and reports of illness or injuries to subjects.

5.1.2 Minutes of IRB meetings shall include members, alternates, and visitors in attendance at the meetings; actions taken by the IRB; the vote on these actions, including the number voting for, against, and abstaining; the basis for requiring changes in or disapproving research; a written summary of the discussion of controversial issues and resolutions of same; and a statement for each approved proposal that the proposal is approved and all IRB concerns have been addressed. Minority reports shall be filed in all cases in which there is no consensus.

5.1.3 Records of continuing review and monitoring activities.

5.1.4 Copies of all correspondence between the IRB, the investigators, and between other NASA Centers, including NASA HQ.

5.1.5 A list of IRB members identified by name, earned degrees, representative capacity, areas of proficiency such as board certification and licenses, and any current or previous employment or other relationship between each member and NASA or NASA contractors. A copy of this list and changes including IRB members' continuing education thereto shall be forwarded to the ANO yearly or as updated.

5.1.6 Written procedures for the operation of the IRB.

5.1.7 Statements of significant new findings provided to subjects, as required below by section 8.5.5 of this NPR.

5.1.8 Written procedures for assuring prompt reporting to the IRB and the ANO of any problems, whether anticipated or not, involving risks to subjects or to others; serious noncompliance or continuing noncompliance with NASA research policy, with the PI's protocol, or with the requirements of the IRB; or suspension or termination of IRB approval.

5.1.9 An annual report of IRB activities based on the minutes.

5.2 Record-Retention Requirement

IRB records relating to research conducted by an investigator shall be retained for at least 3 years beyond the last action of the IRB on that protocol or specific issue. The IRB shall retain records that shall then be dispositioned in accordance with NPR 1441.1, NASA Records Retention Schedules. All records shall be entered into a secure database, under the management of the Recording Secretary of the IRB, and accessible for inspection and copying by authorized representatives of NASA at reasonable times and in a reasonable manner. The information contained in the records and the database shall be maintained in conformity with prescribed NASA policies, guidelines, and procedures.

CHAPTER 6. NASA Flight IRB (NFI)

6.1 Establishment of NASA Flight IRB

The ANO shall establish a NASA Flight IRB whose function is to review all research proposals that (1) propose the use of crewmembers as research subjects and/or research technicians; (2) all space flight or aircraft research proposals that use noncrew human research subjects; (3) all aircraft research proposals that use noncrew as research technicians if it is deemed that their participation could effect their health or safety; and (4) all space flight or aircraft research proposals that use animals, biological, or toxic materials that could be expected to interact with the humans onboard the space or aircraft. The NFI may also evaluate other proposals at the discretion of the ANO.

6.2 NFI at Johnson Space Center (JSC)

The NFI shall be located at JSC; however, meetings of the NFI may be at any appropriate location.

6.3 Membership

In consultation with the JSC Center Director, the ANO shall appoint the membership of the NFI which shall include (1) the Chairperson; (2) a NASA safety representative; (3) an active NASA Astronaut; (4) a NASA flight surgeon (5) a non-NASA employee from the bioethics or health profession communities; and (6) other members as required to have sufficient expertise and diversity to adequately evaluate research proposals. The Center Office of Chief Counsel or the Headquarters Office of General Counsel (OGC), as appropriate, shall provide legal advice to the NFI.

6.4 Conflict of Interest

No NFI member may participate in the review of any proposal in which that member has a conflicting interest, except to provide information requested by the Board.

6.5 Ad hoc Members

The NFI may invite nonvoting experts to help review and resolve special or difficult issues, which require competence beyond or supplementing that available on the Board.

6.6 Recording Secretary

The recording secretary shall be appointed by the Chairperson of the NFI for recordkeeping and for general administrative Board functions.

6.7 Term of Membership

NFI members shall be appointed for a 3-year term and can be reappointed at the end of their term. NFI members may not be removed from their positions before the end of their terms except in cases of misconduct.

6.8 Research Monitor

The NFI may require that a NASA safety and health monitor (which may be the crew surgeon) must be available to

observe all research studies involving NASA crewmembers.

6.9 PI Certification of Safety and Health Risks

If human subjects are to participate in multiple flight research protocols at the same time, the NFI shall review all the research proposals as an integrated protocol to assess the risks to the research subject.

6.10 Integrative Proposal Review

All research proposals that are required for review by the NFI shall be approved by the NFI prior to the initiation of crew or subject briefing.

6.11 IRB Approval Prior to Beginning of Training

The NFI will review only those proposals that have undergone successful scientific peer review, are funded for definition and/or feasibility studies, and are proposed as part of a flight payload complement.

6.12 No Waiver or Reciprocity With Any Other IRB

No waiver or reciprocity with any other IRB shall be accepted for any research proposal falling under chapter 6.

6.13 NFI Conform With NPR

The NFI shall conform to all appropriate parts of this NPR.

CHAPTER 7. Informed Consent

7.1 Required Informed Consent

Except as provided in section 7.6 below, no PI may involve a human subject in research covered by this NPR unless the PI has obtained the informed consent of the subject or the subject's legally authorized representative. Such consent shall be sought only under circumstances that provide the prospective subject, or the subject's representative, with sufficient latitude and opportunity to decide whether or not to participate, while minimizing the possibility of coercion or undue influence. All information that is provided shall be in language understandable to the subject or the representative. No informed consent may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or which releases, or appears to release the PI, the sponsor, the institution, or its agents from liability for negligence.

7.2 Elements of Informed Consent

The following basic elements of informed consent information shall be provided to each subject in nontechnical, easily understood language:

7.2.1 A statement that explains that the study involves research. An explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

7.2.2 A description of foreseeable risks or discomforts to the subject.

7.2.3 A description of any benefits to the subject, or to others which may reasonably be expected from the research, or a statement that the research is of no benefit to the subject.

7.2.4 A disclosure of appropriate alternative procedures or courses of action or treatment that could be advantageous to the subject.

7.2.5 A statement describing the extent to which confidentiality of records identifying the subjects shall be maintained. (Special attention should be given to explaining the problem of maintaining confidentiality with electronically stored databases.)

7.2.6 For research involving more than minimal risk, an explanation as to whether any compensation and medical assistance are available if injury or illness occurs and, if so, of the specifics relating thereto and any other relevant information.

7.2.7 Identification of contacts for answers to pertinent questions concerning specifics of the research and the research subject's rights. The contact in the event of a research-related injury or illness to the subject should also be identified.

7.2.8 Except as provided in sections 7.4.2 and 7.4.4 below, a statement that participation is voluntary, and that subjects have the right to refuse to participate and to discontinue participation in the research at any time and that they may do so without penalty or loss of benefits to which they would be otherwise entitled. If the subject, in fact, cannot withdraw at any given time (because it would be unwise, dangerous, or impossible), the circumstances must be explained to the subject in writing as part of the informed consent document.

7.2.9 Subjects concerned about protocol violations may request a meeting with the relevant IRB.

7.3 Subject Withdrawal From Nonspace-Based Research

7.3.1 Consideration for withdrawal from nonspace-based research is predicated upon the following:

7.3.2 Research subjects may withdraw from participation at any time without penalty or loss of benefits to which they are otherwise entitled.

7.3.3 In the event that a subject withdraws from nonspace flight research involving human subjects, NASA reserves the right to replace that individual with another test subject.

7.4 Subject Withdrawal From Space-Based Research

Consideration for withdrawal from space-based research includes the following:

7.4.1 Research subjects may withdraw from participation at any time without penalty or loss of benefits to which they are otherwise entitled.

7.4.2 In the event that the research subject is a crewmember,

7.4.2.1 The IRB-approved life science experiment is part of the central or core function of the mission,

7.4.2.2 The crewmember was clearly and completely informed of the experiment prior to assignment to the mission,

7.4.2.3 The crewmember formally consented to participate in the experiment,

7.4.2.4 No substantial change has occurred in the protocol since the crewmember's consent; and

7.4.2.5 No new interim scientific information has surfaced indicating that the initial protocol presents a more than minimal increase in health or medical safety risk and no new, safer techniques have become available; then

7.4.2.6 Withdrawal from research may result in removal of that individual from that mission. This action shall be based on the determination that it is in the best interest of the Government and to ensure mission success.

7.4.3 The determination of whether all conditions in section 7.4.2 have been met shall rest with the IRB that approved the initial protocol. In the case of NASA or international astronauts, or payload specialists, a review shall be conducted by the ANO to validate the findings of the IRB under section 7.4.2 and formulate a recommendation. Approval of the recommendation and final disposition shall rest with the AA for OSF in consultation with the mission-sponsoring organization.

7.4.4 When a crewmember has withdrawn and all conditions in section 7.4.2 have been met, such withdrawal shall not influence career opportunities; however, it could be used in the decision process regarding assignments to a future mission in which similar life science experiments are central or core to the mission.

7.5 Supplementary Elements of Informed Consent

Additional elements of informed consent may include, when appropriate, one or more of the following elements of information:

7.5.1 A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus if the subject is or may become pregnant), which are currently unforeseeable.

7.5.2 Anticipated circumstances under which the subject's participation may be terminated by the PI without regard to the subject's consent.

7.5.3 Any additional monetary costs to the subject that may result from participation in the research.

7.5.4 The consequences of a subject's decision to withdraw from the research and prescribed procedures for an orderly termination of participation by the subject.

7.5.5 A statement that the subject shall be informed of significant new findings developed during the course of the research, including adverse reactions of other subjects participating in this research, which may affect the subject's willingness to continue participation.

7.5.6 The approximate number of subjects in the study.

7.5.7 Any collective impact of multiple protocols, if applicable.

7.5.8 PI disclosure of financial interest in the research study, to include the benefits the PI will derive from the study, or drugs or devices being developed through the study.

7.6 Waiver of Consent Elements

An IRB may approve a consent procedure that either does not include or otherwise alters some or all of the elements of informed consent set forth in this NPR; or the IRB may waive the requirements to obtain informed consent, provided that the IRB finds and documents each of the following:

7.6.1 The research involves no more than minimal risk to the subjects.

7.6.2 The waiver or alteration shall not adversely affect the rights and welfare of the subjects.

7.6.3 The research could not practically be carried out without the waiver or alteration.

7.6.4 Whenever appropriate, the subjects shall be provided with additional pertinent information after participation.

7.6.5 Published or released astronaut data and other human experimental data derived from or associated with such approved research shall not be attributable to any individual.

7.7 NPR Shall Not Preempt Current Laws

The informed consent requirements in this NPR shall not preempt any applicable Federal, State, or local laws that require additional information to be disclosed in order for informed consent to be legally effective.

7.8 Physician Right to Practice Emergency Medicine

Nothing in this NPR is intended to limit the authority of a physician to provide emergency medical care to the extent that the physician is permitted to do so under applicable Federal, State, or local law.

CHAPTER 8. Documentation of Informed Consent

8.1 Written Consent Required

Informed consent shall be documented by the use of a written consent form approved by the IRB, and signed and dated by the subject or the subject's legally authorized representative. The PI shall keep the original signed consent for at least 3 years after the completion or termination of the research protocol; and a copy shall be given to the person signing the form. The PI must make the signed consent form available to the IRB for inspection and copying.

8.2 The Consent Form May Be Either of the Following

8.2.1 A written consent document containing the elements of informed consent required in chapter 7 of this NPR. This form may be read to the subject or the subject's legally authorized representative, but in all instances, the PI shall give either the subject or the representative adequate opportunity to read, understand, ask questions, and consult with additional experts if so desired before it is signed.

8.2.2 A "short form" written consent document stating that the elements of informed consent required in chapter 7 has been presented orally to the subject, or the subject's legally authorized representative. When this method is used, there shall be an independent witness to the oral presentation. Also, the IRB shall approve a written summary of that which is to be said to the subject or the representative. Only the "short form" itself is to be signed by the subject or the representative. However, the witness shall sign both the "short form" and a copy of the summary. The person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the "short form."

CHAPTER 9. Criteria for IRB Approval of Research Involving Human Subjects

9.1 The following requirements must be satisfied for the IRB to approve the research involving human subjects covered by this NPR:

9.1.1 The PI shall always protect the safety and minimize health risk to subjects: (1) by selecting methodologies and procedures which are consistent with sound research design and conduct and which do not unnecessarily expose subjects to undue risk; and (2) whenever possible, by using procedures already being performed on the subjects for other experiments, so as to minimize the collective impact of multiple protocols on the subject.

9.1.2 In evaluating safety risks and benefits, the IRB shall ensure that risk to subjects be reasonable in relation to anticipated benefits, if any, and the importance of the new knowledge that may reasonably be expected to result. The IRB should consider only those risks and benefits, taking into account the collective impact of multiple protocols that may result from the research. The IRB should not consider possible long-range effects of new knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks or benefits that are its responsibility.

9.1.3 The PI shall obtain and document the voluntary informed consent of each prospective subject or the subject's legally authorized representative. The human research consent form shall contain at least all elements listed in section 7.2 (and section 7.5, if appropriate). The PI shall inform the subject that not all risks are readily identifiable.

9.1.4 The PI may ensure that the subject or the subject's beneficiaries receive compensation by means of insurance, worker's compensation, or the like in the event that the subject suffers illness, disease, injury, loss, or death as a direct result of the research. The lack of this provision may serve as a basis for disapproval of the research. Such provisions for compensation shall be required for all studies performed at a NASA Center.

9.1.5 Where applicable, the research proposal shall contain provisions for monitoring the data collected to ensure the safety of the subjects. Other informational items that should be included in a human research proposal are listed in Appendix A.

9.1.6 The PI shall provide safeguards to protect the privacy of subjects and the confidentiality of data, especially electronically stored data. Biomedical data, if held by NASA and if retrievable by personal identifier, are subject to the Privacy Act of 1974, as amended, 5 U.S.C. 552a, and are maintained under the NASA System of Records, Human Experimental and Research Data (HERD) Records. Such data held by other institutions must have similar safeguards. The PI shall maintain the records relating to the conducted research and shall retain these records for at least 3 years after completion of the research.

9.1.7 No human subject shall participate in any portion of the research until the protocol is approved by the IRB.

9.1.8 The PI shall ensure that selection of subjects is equitable and representative of the population that its biomedical research intends to represent. The IRB should assess the purposes and setting of the research. In the case of space flight, considerations should be given to the habitability conditions and the level of medical care available in the event of illness or injury.

CHAPTER 10. Expedited Review

10.1 Minimal Risk

In the case of research involving minimal risk to human subjects (Appendix B), the IRB may conduct an expedited review. This shall consist of a review by the Chairperson or one or more experienced reviewers designated by the Chair from among the members of the IRB. It shall be based on the same criteria as a nonexpedited review but shall not require consideration by the entire IRB. The IRB may also use the expedited procedure to review minor changes in previously approved research during the period for which approval is authorized.

10.2 Authority of Expedited Reviewer

In conducting an expedited review, the reviewer(s) exercises all the authority of the IRB, except that the reviewer(s) may not disapprove the research. A research activity may be disapproved only through the nonexpedited procedure described in this NPR. A reviewer must recommend that the proposal be reviewed by the full IRB if the research involves more than minimal risk.

10.3 Report to the IRB for Expedited Review

The reviewer(s) who approves research proposals using the expedited review procedure shall either directly or through the Chairperson report to the Board on such approvals at the next meeting of the IRB. The minutes of the IRB shall reflect the expedited approval with the concurrence of the full IRB.

CHAPTER 11. Reports on Injuries, Illness, or Disease and Medical Care

11.1 PI Responsibility for Reporting

The PI shall immediately inform the IRB Chairperson and initiate appropriate investigations in the event of the following:

11.1.1 Any injury, illness, disease, or death, whether expected or not, incurred by the subject as a possible result of a research protocol.

11.1.2 Any change in the experimental environment or in the subject that could forecast medical problems.

11.2 PI Responsibility for Recordkeeping

The occurrence of any instance requiring medical attention. The PI shall note any such occurrences in the subject's research records and make them available to the subject's physician.

11.3 Determination of Suspension of Research

The IRB Chairperson or designate shall determine whether the research should be immediately suspended with subsequent IRB concurrence.

11.4 Reporting to NASA Headquarters

The PI shall report all such events immediately to the IRB. If appropriate, the PI shall report all such events additionally to NASA. A non-NASA PI shall notify all institutional IRB's that approved his or her proposal. It shall be the responsibility of said IRB's holding approved MPA's from other Federal agencies to communicate such incidents to that Agency directly.

11.4.1 When the injury results in a loss of life, a permanent disability, or when a person requires hospitalization, and/or a person requires extensive first aid or lost workday(s), the mishap must be reported to NASA HQ immediately (within 1 hour) in accordance with NPD 8621.1, NASA Mishap and Close-Call Reporting, Investigating, and Recordkeeping Policy, and NPR 8621.1, NASA Procedures and Guidelines for Mishap Reporting, Investigating, and Recordkeeping.

11.4.2 The IRB Chairperson shall notify the NASA Center Safety Officer; the ANO; and the Crew Medical Officer especially in the case of crew involvement in the event of a reportable incident. The IRB Chair shall initiate an investigation as soon as possible per NPR 8621.1, NASA Procedures and Guidelines for Mishap Reporting, Investigating, and Recordkeeping.

11.4.3 When NASA conducts a mishap investigation to investigate an injury or illness resulting from the research, all researchers shall cooperate with the NASA mishap investigators, grant interviews, and provide data as requested.

11.5 Review by IRB Required to Resume Research

Once a research protocol involving human subjects is suspended, IRB review and approval are required before the experiment can resume.

11.6 Health Care Provisions for Research Subjects

11.6.1 The NASA IRB shall review the health care provisions provided to the research subject, and/or available for possible injury or illness that could occur during the research.

11.6.2 The provisions for access to medical care shall be included in the consent form as appropriate.

11.6.3 The medical care for astronaut research subjects shall include the assigned NASA flight surgeon. The flight surgeon shall have access to all research data that pertains to the health of the astronaut research subject. The flight surgeon may use this data for the ongoing health monitoring of the astronaut.

CHAPTER 12. Protocol Modifications

12.1 IRB Review of Protocol Modifications

The protocol shall not be modified unless the IRB or the reviewer (in the case of an originally expedited review) approves a formal request with appropriate justification. If the IRB determines that the modification increases the risk(s) to the subject, a revised informed consent shall be required.

12.2 Peer Review Suggested Modifications

Space flight experiment research protocols may require modification during flight, as procedures are refined to comply with operational constraints. Substantive human research protocol changes during flight require the majority approval of a quorum of the IRB. The Chairperson or designee shall expeditiously seek this approval in a meeting or by teleconferencing, if appropriate, with members of the IRB. The Mission Operations Control Room Surgeon must be immediately informed of this requested substantive change and has the authority to temporarily suspend the experiment until the IRB can review the request. All such approved changes to the research protocol shall also be approved by the crewmember volunteering for the research prior to the initiation of the research protocol changes.

CHAPTER 13. Assurances from Participating Instructions

13.1 MPA on File

All NASA Centers or other institutions proposing research involving human subjects supported by NASA shall give written institutional assurance, as provided in 14 CFR 1230.103, to the ANO. An MPA on file with the DHHS OHRP shall satisfy this requirement. Assurances from international institutions must follow the U.S. ethical and legal standards.

13.2 NASA IRB Approvals and Non-NASA Research

NASA IRB review and approval shall be required for any protocol by a non-NASA investigation, which utilizes NASA facilities, equipment, or personnel in addition to the IRB of the extramural participants. Therefore, in this instance, other institutional assurances certified by DHHS OHRP or international oversight bodies for extramural projects shall not suffice.

13.3 Format for MPA

Institutions submitting MPA's and SPA's to NASA should use the sample documents from the DHHS OHRP deleting DHHS, or OHRP and substituting NASA.

13.4 Term of MPA

The term of an MPA shall not exceed 5 years.

CHAPTER 14. The Approval of Assurances

14.1 Approval by Authorized Official

The ANO with the concurrence of the OGC shall evaluate the MPA's from NASA Centers and shall certify such MPA's that are deemed appropriate for the protection of human subjects if the submissions are satisfactory and meet the requirements in NPD 7100.8, Protection of Human Research Subjects, and this NPR (NASA Centers not conducting or supporting human research shall file an annual notice with the ANO).

14.2 Non-NASA Institutions

Other interested institutions, including public, private, and international institutions may submit an application for a NASA-approved MPA. The ANO with the concurrence of the OGC may evaluate these MPA's and may certify such MPA's that are deemed appropriate for the protection of human subjects if the submissions are satisfactory, meet the requirements in NPD 7100.8, and this NPR, and are in NASA's best interests.

14.3 Site Review

A site visit may be required for evaluation of either a new or renewal MPA to assess the adequacy of the NASA Center or other institution's procedures for protecting human research subjects. The site visit for a new approval shall evaluate the facilities to determine (1) the institution's ability to safely perform research involving human subjects, (2) the expertise of the officials who shall oversee the assurances, (3) the facilities for maintaining adequate records, and (4) the institutional commitment for adequately funding the oversight efforts. Compliance may be audited at a site visit for renewal or at other times. Training of IRB and staff members shall also be monitored.

14.4 Evaluation of Requirements for MPA Approval

Approval of an MPA shall be based on the evaluation of the following factors: (1) administration including jurisdiction of the IRB, establishment and membership of the IRB, recordkeeping, institutional responsibilities, the assurance itself, staff, space, and supplies, communication, institutional procedures and guidelines, identification of the authorized NASA Center or other institutional official, training of IRB and staff members, and process for internal audits; (2) regulations and policies regarding Federal laws and the common rule and their use by the IRB;(3) description of the way the IRB interacts with other interested oversight bodies, e.g. safety, legal, (4) basic IRB review policies including risk or benefit analysis, requirement for the disclosure of risks and benefits in the consent form, continuing review and monitoring of data, requirements and documentation for the informed consent; (5) policies for monitoring and observation of research activities; and (6) appropriate guidelines for the use of special classes of subjects.

CHAPTER 15. Assurance Compliance Oversight Procedures

15.1 Allegations on Noncompliance

The ANO shall investigate any allegation or indication of noncompliance with NPD 7100.8, or with this NPR, which comes to his or her attention with regard to NASA-conducted or supported research. The ANO may at any time modify an MPA to require interim corrective actions to remedy such noncompliance. The ANO may also suspend an MPA during an investigation if it is necessary to protect human research subjects.

15.2 Center Responsibility

The ANO may request the NASA Center or other institution to either acknowledge the institution's report of noncompliance or notify the NASA Center or institution's Assurance Signatory Official (ASO) of the possible noncompliance and, as necessary, request that the institution investigate the matter and report back. The ANO may communicate directly with other affected institutional officials or personnel or, if the noncompliance involves a specific research investigator, may notify that investigator directly.

15.3 Onsite Evaluation

The ANO may initiate an onsite evaluation of protections under an MPA even in the absence of specific allegations or indications of noncompliance. The ANO may convene a NASA HQ review panel to investigate the circumstances surrounding any cases of noncompliance. A designated senior NASA HQ official who has no apparent or real conflict of interest shall chair the review panel. The membership shall consist of five members, as a minimum, with participation from the OGC and the OSMA. After review of the circumstances, the ANO in consultation with the OGC may prescribe and publicize sanctions, as appropriate.

15.4 Reporting Requirements

If the Authorizing Official determines that a formal report of findings is warranted, he or she shall notify the NASA Center or other institution's ASO that a formal report is required. The report may include (1) an invitation to the Signatory Official for institutional identification of errors of fact, and/or (2) the complainant(s), as appropriate, with an invitation for individual identification of errors of fact.

15.4.1 The Authorizing Official will establish a Data Safety Monitoring Board (DSMB) to review clinical studies as appropriate.

15.4.2 The DSMB membership will be multidisciplinary in nature and, as a minimum, will include experts in biostatistics, experimental design, and bioethics. The DSMB will be established for particularly high-risk research, or research where the blinded nature of data might put subjects at risk in ways that are not immediately apparent to blinded researchers.

15.4.3 The relevant IRB's, in consultation with the Office of CHMO, will determine which protocols warrant the establishment of particular levels of DSMB oversight.

15.4.4 All investigators who work with human subjects must be trained in basic principles of human subjects protection. Minimum training should include the history and basic principles of human subject research protections, risk or benefit assessment and informed consent procedures, and institutional responsibilities. Research investigators must demonstrate that they have completed such training to be eligible to submit research proposals to a NASA IRB.

CHAPTER 16. Sanctions and Potential Disciplinary Action

16.1 PI Research Suspended

Any NASA PI participating in research involving human subjects, who does not comply with this NPR or with the IRB-approved protocol, may have his or her research immediately suspended or terminated by the appropriate IRB, NASA Center Director, OBPR Director of Bioastronautics Research, or the ANO. Such noncompliance may be cause for revocation of funding. It may also be the cause for other appropriate remedies including disciplinary action against the PI, i.e. sanctions addressed in this section do not exclude possible personnel actions.

16.2 Non-NASA PI

PI's not employed by NASA, who are responsible for research involving human subjects that is sponsored by NASA or is performed in NASA facilities, aircraft, or spacecraft and who do not comply with this NPG or do not comply with the NASA IRB approved protocol, may have their research immediately suspended or terminated and shall also be subject to appropriate sanctions. NASA shall suspend or terminate funding approval if the investigator's research is suspended or terminated by the originating institution for any reason. NASA may immediately suspend or terminate grant approval for research involving human subjects from non-NASA institutions funded by NASA if that institution's MPA is suspended or terminated.

16.3 Funding of Suspended Research

16.3.1 If an MPA for a NASA Center or any institution is suspended or terminated for cause, the ANO with the concurrence of the OGC and the Office of Procurement may recommend to the NASA Administrator that all NASA funding for human research to that institution be suspended or terminated.

16.3.2 Any evidence of alleged criminal wrongdoing at any level related to information obtained from IRB activities and oversight by the Office of the CHMO shall be forwarded to the NASA Office of the Inspector General.

CHAPTER 17. Measurements

17.1 The following metrics are required:

17.1.1 Number of research proposals reviewed by the IRB and tracking of timely responses to the Board's recommendations (action items) by the PI's.

17.1.2 Number of research proposals reviewed by the IRB and tracking of timely PI responses to the Board's recommendations (action items) and the number of proposals approved and disapproved by the IRB.

17.1.3 Number of research proposal renewals.

17.1.4 Number of adverse reactions or equipment failures or modifications reported to the IRB by the PI, the IRB Compliance Officer (if mandated), crew surgeon, or other responsible monitors or officials.

17.1.5 Tracking of action item responses from PI's.

17.1.6 Number of IRB letters of reprimand or more serious sanctions imposed.

17.1.7 Number of audits and followup corrective actions adopted as a result of complaints to the IRB.

17.1.8 Number of official mishap investigations instituted or completed and corrective action taken to avoid repetitions.

17.1.9 Number of cases of research misconduct occurring in IRB-approved protocols.

17.1.10 Number of investigators taking the NASA Bioethics training. Number of first-time training certifications versus number of recertifications.

17.1.11 Number of DSMB reviews, corrective actions, and lessons learned.

APPENDIX A: Definitions

1. Assurances are either a Single Project Assurance (SPA) or Multiple Project Assurance (MPA) which is a formal, written statement in which an institution promises to comply with applicable rules governing research with human subjects. An SPA or MPA must be provided by the IRB prior and accepted by the appropriate Federal agency prior to commencing of any NASA research involving human subjects. An SPA or MPA must cover all research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States.

2. Authorized NASA Official (ANO) is the official designated by the NASA Administrator who is empowered, subject to conditions and limitations imposed by an immediate supervisor, to authorize research involving human subjects. This has been designated in NPD 7100.8D as the Chief Health and Medical Officer (CHMO).

3. Conducted Research is research involving a PI or subordinate researcher who is a NASA employee.

4. Crewmember is an astronaut, payload specialist, or aviation personnel assigned to a spacecraft or an aircraft mission who may volunteer as a research subject and/or participate as a research technician for a research experiment as part of their employment.

5. Funded Research is research that is partially or completely underwritten by NASA through a contract, cooperative agreement, grant, or other funding mechanism, and which does not also involve permission by NASA to utilize NASA, U.S. Government, or foreign agency facilities, equipment, or personnel, including space and aircraft vehicles.

6. Human Subject is a living person who is an integral part of a test, or other substantive evaluative procedure and about whom the PI (whether professional or student) obtains (1) research data through intervention or interaction; or (2) identifiable private information.

7. Informed Consent consists of oral or written acknowledgement by a research subject that he/she understands the nature of the research to be performed and his/her obligations in participating in the research, the potential risks to health and well-being by participating as a research subject, and other tests or therapies available if the subject is a medical patient seeking health care; that he/she has been allowed to ask questions relating to the research to be performed; and is allowed to quit the research activity at any time (except if it would cause greater harm to the subject). The elements of informed consent are full disclosure, adequate comprehension, and voluntary choice to and for the research subject.

8. An Institutional Review Board (IRB) is a committee approved by NASA and established in accordance with this NPG or approved by the DHHS under a current Multiple Project Assurance (MPA) to review research involving human subjects and their activities for the adequacy of procedures that protect human subjects in research.

9. Interaction includes communication or interpersonal contact between the investigator and the subject.

10. Intervention includes both physical testing procedures by which data are collected (for example, equipment used on a person) and manipulation of the subject or the subject's environment for research purposes.

11. Life Sciences Research includes biomedical, biological, human factors, psychological, environmental health, and life-support experimentation.

12. Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Persons employed in hazardous occupations are not expected to submit to greater risks than persons employed in non-hazardous occupations. Examples of minimal risk activities are presented in Appendix B.

13. Principal Investigator is the researcher who has overall responsibility for all aspects of the funded and/or sponsored research project.

14. Private information includes information provided for specific purposes about a subject's medical, physiological, or behavioral status or history about which the individual can reasonably expect that no observation or recording is taking

place and which the individual can reasonably expect shall not be made public.

15. Research is a systematic investigation, including development, testing, and evaluation, which may be designed to test a hypothesis, enable conclusions to be drawn and, thereby, develop or contribute to knowledge in general. The research is described in a formal protocol that sets forth an objective and a set of procedures designed to reach the stated objective.

16. Risk: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk."

17. Serious Harm is a temporary or permanent illness, injury, disability, or death.

18. Sponsored Research is investigative and commercial experimental work approved by NASA to permit the utilization of NASA, U.S. Government, or foreign agency facilities, equipment, or personnel, including space and aircraft vehicles, whether or not NASA funds are used to support the research.

19. Supported Research is NASA-funded or -sponsored research.

APPENDIX B: Mandatory Portion of a NASA Human Subject Research Proposal

The following information shall be included with the proposal submitted for IRB review:

1. Name of the organization conducting the research or for which the research is being conducted.

2. Name and qualifications of persons who shall conduct the research involving human subjects.

3. The reasons for the use of human subjects and a plan to ensure equitable selection of research subjects with reference to race and gender.

4. Possible inconveniences, discomforts, illnesses, diseases, injuries, pain, and risks to the subject.

5. A description of the hazard controls and safety precautions to be applied.

6. Expected duration of the study, including approximate beginning and ending dates.

7. The extent of any physical examinations to be given by medical personnel:

a. Initially, to ascertain the subject's health status and to certify that the subject is capable of undertaking the proposed research,

b. During the course of the research, and

c. At the completion of the research.

8. Wage, salary, or other payment, if any, to be paid to the subject for participating in the research.

9. Source (Federal or State compensation acts and insurance) and general description of compensation, if any, to be received by a subject or the subject's legally authorized representative in the event of injury or death. Assistance in the preparation of this information may be obtained from the appropriate NASA Center OGC or, if the subject is or shall be a Government employee, from the NASA Center Personnel Office.

10. Availability of medical personnel, if applicable, and an adequate medical facility within a reasonable distance of the location where research is performed. Indicate whether a physician shall be present at all times or on call; if on call, the physician's location during the research.

11. Information about the research involving human subjects that shall be given to the subject while obtaining the subject's informed consent.

12. The research involving human subjects consent form, including the provision that subjects concerned about protocol violations may request a meeting with the relevant IRB.

13. Evidence of review and approval by the sponsoring organization's IRB.

14. A plan for ensuring privacy and protecting the confidentiality of data with particular attention to data contained in an electronic database.

15. Data Safety Monitoring plan, where applicable.

APPENDIX C: Types Of Researh Activities That May Be Reviewed Through Expedited Review Procedures

Research activities involving no more than minimal risk and in which the involvement of human subjects shall be in one or more of the following categories (carried out through standard methods), may be reviewed by the IRB through the expedited review procedure authorized in Federal Policy Regulations cited in 45 CFR 46.110 and 14 CFR 1230.110.

1. Collection of hair and nail clippings, in a nondisfiguring manner, deciduous teeth, and permanent teeth if normal preventive patient care indicates a need for extraction.

2. Collection of excreta and external secretions, including sweat, noncannulated saliva, and placentas removed at delivery, and amniotic fluid at the time of membrane rupture prior to or during labor.

3. Recording of data from subjects 18 years of age or older, using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body, or at a distance, and do not involve input of matter or significant amounts of energy into the subject or an invasion of privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, and detection of naturally occurring radioactivity, diagnostic sonography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (e.g., X-rays, microwaves, ultraviolet light, and infrared lights).

4. Collection of both supra and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

5. Voice recordings made for research purposes such as investigations of speech defects or stress.

6. Moderate exercise performed by healthy subjects.

7. The study of existing data, documents, records, pathological specimens, or diagnostic specimens. In the latter two instances, a new informed consent statement must be obtained.

8. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, in which the PI does not manipulate the subject's behavior and the research does not involve stress to the subjects.